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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,107	08/21/2001	Lars A. Hanson	003300-723	5780

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EXAMINER	
KAM, CHIH MIN	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 12/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/743,107	HANSON ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *54-86 and 98* is/are ~~allowed~~. free of art.

6)☒ Claim(s) *87-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

1. Claims 54-98 are pending.

Applicants' amendment filed September 25, 2003 is acknowledged, and applicants' response has been fully considered. Claims 54, 56-61, 64-66 and 77-79 have been amended, and a new claim 98 has been added. Therefore, claims 54-98 are examined.

2. The formal drawings of Figs 1-5B filed September 25, 2003 have been received, however, the drawings of Figs 2, 4A and 4C have been partly obliterated by date stamps, please resubmit the drawings of Figs 2, 4A and 4C.

Objection Withdrawn

3. The previous objection of the disclosure (page 6) and claims 54 and 56 is withdrawn in view of applicants' amendment to the disclosure and the claim, and applicants' response at pages 2, 12 and 13 in the amendment filed September 25, 2003.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

4. The previous rejection of claims 54, 56-66, 72, 74, 75 and 77-86, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 13-14 in the amendment filed September 25, 2003.

5. The previous rejection of claims 54-86, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 14-15 in the amendment filed September 25, 2003.

Claim Rejections - 35 USC § 102

6. The previous rejection of claims 54, 56, 60, 75, 77, 82, 83, 85, 87, 92, 94 and 96 under 35 U.S.C. 102(b) as being anticipated by Tomita *et al.* (EP 0629347), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 15-16 in the amendment filed September 25, 2003.

7. The previous rejection of claims 54, 56, 60, 66, 75, 77, 82, 83, 85, 87, 92, 94 and 96 under 35 U.S.C. 102(b) as being anticipated by Tomita *et al.* (U. S. Patent 5,304,633), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 15-16 in the amendment filed September 25, 2003.

8. The previous rejection of claims 54, 56, 58, 60, 65, 72-75, 77, 81, 82, 85, 87, 92, 93 and 96 under 35 U.S.C. 102(b) as being anticipated by Yamamoto *et al.* (U. S. Patent 5,565,425), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 15-16 in the amendment filed September 25, 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 87-97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating inflammations or infections comprising administering a lactoferrin peptide comprising SEQ ID NO:99, wherein SEQ ID NO:38 is excluded, does not reasonably provide enablement for a method of preventing (not even occurring in the first time) inflammations or infections comprising administering a lactoferrin

peptide comprising SEQ ID NO:99, wherein SEQ ID NO:38 is excluded. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 87-97 are directed to a method of treating or preventing inflammations or infections comprising administering a lactoferrin peptide comprising SEQ ID NO:99, wherein SEQ ID NO:38 is excluded. The specification, however, only discloses cursory conclusions without data supporting the findings, which states that modified peptides from amino acid residues 20-31 of human lactoferrin, or functionally equivalent homologs or analogs of the peptides can be used for treating or preventing infections or inflammations (page 4). There are no indicia that the present application enables the full scope in view of a method of treatment or prevention of infections or inflammations using the lactoferrin peptide as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the absence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses unspecified variants the treating conditions for preventing infections or inflammations using the lactoferrin peptide, which are not adequately described or demonstrated in the specification.

(2). The absence or presence of working examples:

The specification discloses treating infections or inflammations using the lactoferrin peptides (Examples 3-19 and 25-28, Figs 1-5), however, there are no working examples indicating the prevention of infections or inflammations using the lactoferrin peptides.

(3). The state of the prior art and relative skill of those in the art:

The related art (Tomita *et al.*, EP 0629347; Tomita *et al.*, U. S. Patent 5,304,633; Yamamoto *et al.*, U. S. Patent 5,565,425) indicates the analogs of lactoferrin peptides with defined sequences have antimicrobial activities. However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the treating conditions for preventing infections or inflammations using the lactoferrin peptides, and effects of the peptides in the prevention of diseases to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

The claims encompass a method for treating or preventing infections or inflammations comprising administering a lactoferrin peptide comprising SEQ ID NO:99, wherein SEQ ID NO:38 is excluded. However, the specification does not indicate the treating conditions for preventing infections or inflammations using the lactoferrin peptides, nor demonstrates how infections or inflammations being prevented. Therefore, it is unpredictable regarding the effect the lactoferrin peptides in the method of preventing infections or inflammations.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method of treating or preventing inflammations or infections comprising administering lactoferrin peptides. The specification indicates the antimicrobial activities of various lactoferrin peptides such as peptides of SEQ ID NO:99 (Examples 3-19 and 25-28, Figs 1-5). However, the specification does not provide any specific guidance on how to prevent inflammations or infections using the lactoferrin peptide, e.g., the treating conditions such as the dose to prevent the disease, or if the disease does not occur, how to monitor it. Moreover, there is no working example indicating the effect of the lactoferrin peptide in preventing inflammations or infections. Therefore, it is necessary to have additional guidance on the treating conditions for preventing inflammations or infections and on the methods for monitoring the disease which has not occurred, and to carry out further experimentation to assess the effect of the lactoferrin peptide in the prevention of inflammations or infections.

(6). Nature of the Invention

The scope of the claims encompass a method for treating or preventing infections or inflammations comprising administering a lactoferrin peptide, but the specification only shows the treatment of infections or inflammations using the lactoferrin peptide, it does not demonstrate how to prevent infections or inflammations using the lactoferrin peptides. Thus, the disclosure is not enabling for the reasons discussed above.

In summary, the scope of the claim is broad, while the working example does not demonstrate the prevention of disease in the claimed method, the effect of the peptide is unpredictable in the prevention of diseases, and the teachings in the specification are limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effect of the lactoferrin peptide in preventing infections or inflammations.

In response, applicants have amended claims to remove the phrase "or a functionally equivalent homolog or analog thereof". The response has been considered, and the argument regarding the lactoferrin peptide is persuasive, thus the rejection of claims 54, 56-66, 72, 74, 75 and 77-86 is withdrawn. However, there is no response regarding the method of preventing infections or inflammations using the lactoferrin peptides, thus claims 87-97 remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 87-97 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 87-97 are indefinite because the claim lacks an essential step in the method of treating or preventing infections or inflammations. The omitted step is the outcome of the process. Claims 88-97 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate claims 87-97 recite a proper method step such as administering to a patient in need thereof an effective amount of peptide of claim 54. The response has been fully considered, however, the argument is not persuasive because the claim does not include the endpoint of treatment, thus it is not clear whether the treatment is effective in a method claim. Use of the phrase "administering to a patient in need thereof an amount effective to reduce infections or inflammations" is suggested.

Conclusion

11. Claims 87-97 are rejected, and claims 54-86 and 98 are free of prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

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December 8, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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